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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,066	12/18/2001	Loren J. Field	7037-450	3713

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EXAMINER	
SULLIVAN, DANIEL M	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 06/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/024,066	FIELD ET AL.	
	Examiner	Art Unit	
	Daniel M. Sullivan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 December 2005 and 21 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *51,52 and 85-90* is/are pending in the application.

4a) Of the above claim(s) *85-90* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *51 and 52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/20/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is a response to the Papers filed 20 December 2005 and 21 April 2006 in response to the Non-Final Office Action mailed 20 July 2005. Claims 51 and 52 were considered in the 20 July Office Action. Claims 51 and 52 were amended and claims 85-90 were added in the 21 April Paper. Claims 51, 52 and 85-90 are pending.

Response to Amendment

Election/Restrictions

Newly submitted claims 85-90 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The claims are directed to a method of obtaining information on the activity of an agent wherein a cardiomyocyte cell of claim 51 or claim 52 is contacted with an agent. As such, the claims are directed to a method of using the claimed product.

The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed can be used in a materially different process, such as to supply cardiomyocytes for immunological analysis or to graft into animals.

Although the Office acknowledges that in the event a product claim is deemed allowable, determining patentability of process claims that depend from or otherwise include all the limitations of the allowable product claim does not impose an undue burden (see below), no such

determination of patentability has been made in the instant case. In the event that the product is not patentable, a determination of whether each method of making and using the product is patentable over the art is based upon the particulars of the method and not on the product made by or used in the method. Conversely, a search of any given process of making or using the product does not adequately support patentability of the product because the product can be made by or used in a materially different process. Therefore, until the product is deemed allowable, search and examination of the process claims with the product imposes an undue burden on the Office. As discussed in detail below, if a product claim is found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04.

Rejoinder in view of *In re Ochiai, In re Brouwer*

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 85-90 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

Claim 51 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Soonpaa *et al.* (1997) *J. Clin. Invest.* 99:2644 (previously made of record) in view of Li *et al.* (1998) *Am. J. Physiol.* 275:H814-H822 and further in view of ENTREZ Nucleotide Database Entry Accession No. M86182 (hereinafter, M86182) for the reasons set forth in the 20 July Office Action commencing at page 3 and herein below in the response to Applicant's arguments.

Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Soonpaa *et al.* (1997) *J. Clin. Invest.* 99:2644 (previously made of record) in view of Li *et al.* (1998) *Am. J. Physiol.* 275:H814-H822 and further in view of ENTREZ Nucleotide Database Entry Accession No. X68452 (hereinafter, X68452) for the reasons set forth in the 20 July Office Action commencing at page 3 and herein below in the response to Applicant's arguments.

Response to Arguments

In response to the *prima facie* rejection of record, Applicant has amended the claims such that they are now directed to an isolated cardiomyocyte, wherein the cardiomyocyte cell exhibits enhanced proliferative potential relative to a control cardiomyocyte cell that does not comprise the introduced nucleic acid molecule.

In the remarks filed in the 20 December Paper, Applicant first contends that the claims are not obvious over the art because Soonpaa *et al.*, the primary reference, discloses expressing cyclin D1 in transgenic animals while the claims recite isolated cells

This argument has been fully considered but is not deemed persuasive because Soonpaa *et al.* does, in fact, teach isolation of cardiomyocytes from the transgenic animals comprising the transgene (see especially the first paragraph on page 2649 and the paragraph bridging pages 2649-2650). Therefore, Soonpaa teaches an isolated cardiomyocyte comprising an introduced nucleic acid molecule encoding a cyclin protein, and for the reasons set forth in the previous Office action, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Soonpaa *et al.* to introduce a nucleic acid encoding the instant SEQ ID NO: 2 or SEQ ID NO: 4.

Next, Applicant contends that it would not be obvious to combine the teachings because Li *et al.* do not report that increasing the level of cyclin D2 in cardiomyocytes is responsible for an increase in hypertrophic growth. Applicant urges that it is no more obvious to express cyclin D2 to induce hypertrophic growth than it would be to induce the expression levels of any of the other proteins whose levels increase during hypertrophic growth.

This argument has been fully considered but is not deemed persuasive. Soonpaa *et al.* expresses a clear interest in analyzing the effect of forced expression of D-type cyclins on DNA synthesis and proliferation of cardiomyocytes (see throughout) and Li *et al.* teaches that several D-type cyclins are induced during hypertrophic growth *in vivo*. Although it is true, as Applicant points out in the remarks, that Li *et al.* makes a distinction between hyperplasia (cell division) and hypertrophy (cell growth), both Soonpaa *et al.* and Li *et al.* teach that the D-type cyclins are known to regulate progression through the cell cycle (see especially Soonpaa *et al.*, Abstract and Li *et al.*, first full paragraph in the right column on page H819). Furthermore, Li *et al.* demonstrates that the hypertrophic response also comprises a shift in the cell cycle profile from

G_0/G_1 to G_2/M (see especially the first full paragraph in the right column on page H819, Figure 6 and the caption thereto), an important step in cell proliferation and evidence of enhanced proliferative potential. Therefore Li *et al.* teaches that the hypertrophic response comprises more than solely an expansion in cell size. Thus, in view of the teachings of Soonpaa *et al.* and Li *et al.* as a whole, the skilled artisan would have been motivated to force expression in cardiomyocytes of any of the D-type cyclins and other cell cycle proteins demonstrated by Li *et al.* to be upregulated in hypertrophy. The fact that one would be motivated to overexpress other proteins as well does not mean that it would not be obvious to overexpress cyclin D2.

In the paragraph bridging pages 5-6 and the first full paragraph on page 6, Applicant points out that hypertrophic growth and cell proliferation are different processes and that the claims recite that increasing the level of cyclin D2 in cardiomyocytes increases proliferation potential of cardiomyocytes. Applicant contends that the claims are directed towards cardiomyocyte proliferation and are not obvious over the disclosure of Li *et al.*, which reports on some changes that cardiomyocytes undergo during hypertrophic growth.

This argument has been fully considered but is not deemed persuasive. It is first noted that the claims recite only that the cardiomyocyte cell exhibits "enhanced proliferative potential" and there is no definition or clear statement of what constitutes enhanced proliferative potential. In particular, the phrase appears to encompass not only proliferating cells but also cells that have some undefined improvement in the capacity to proliferate in the presence of an undefined agent or set of conditions. Therefore, it is reasonable to expect that "enhanced proliferative potential" would result from any alteration that would tend to favor proliferation. Soonpaa *et al.* teaches,

"D-type cyclin/cyclin-dependent kinase (CDK) complexes regulate transit through the restriction point of the cell cycle, and thus are required for the initiation of DNA synthesis" (Abstract). Given this understanding of D-type cyclins, it is reasonable to expect that some finite enhancement in proliferative potential would result from overexpression of cyclin D2, at least, because the proliferative response would not require induction of the endogenous cyclin D2. Therefore, enhanced proliferative potential would not be an unexpected property of any cell overexpressing a cyclin D2.

Applicant's arguments have been fully considered but are not deemed persuasive in view of the record as a whole. Therefore, the claims stand rejected under 35 USC §103(a) as obvious over the art.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

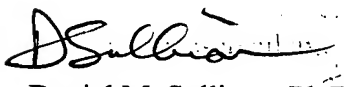
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Friday 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) (http://pair-direct.uspto.gov) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



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Primary Examiner
Art Unit 1636